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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,711	10/20/2003	Keith Rose	3504.244-CON	2597
7590 09/25/2006 Liniak, Berenato & White, LLC Suite 240 6550 Rock Spring Drive Bethesda, MD 20817			EXAMINER HAQ, SHAFIQUL	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TX

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/687,711	ROSE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 20-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 20-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. <u>9/14/06</u>                              |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date <u>10/20/03</u>  | 6) <input type="checkbox"/> Other: _____                           |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 20-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. With respect to claim 1, the term "composition of" should be changed to "composition comprising" to clearly indicate that the composition comprises homogeneous polyoxime molecules component and solid phase component.
4. The term "polypeptide" in line 4 of claim 1 is redundant and should be deleted because baseplate organic molecule is defined in line 5 as "being a polypeptide".
5. With respect to claims 1, 22, 44 and 45, the attachment of the baseplate to solid support is not clear i.e. it is not clear whether baseplate is attached to solid support through side chain of an amino acid of peptide baseplate or through other positions such as amino or carboxy terminal of peptide baseplate.
6. Claim 23 fails to further limit claim 22 from which it depends.
7. Claim 22 recites the phrase "each bond between said baseplate organic molecule and any said second molecules is an oxime bond". The position of oxime bond formation is not clear i.e. it's not clear where on the polypeptide baseplate, this oxime bond formation occurs? Is it on the side chain of amino acids of polypeptide baseplate or on the carboxy terminus of amino terminus of the polypeptide

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baseplate? It is noted that in the argument of 7/6/06, Applicants recited the following phrase in page 12: "Polypeptide baseplate that is bonded to at least two organic molecules through oxime linkages involving the side chains of the amino acids of the peptide baseplate molecule".

8. With respect to claim 25 and 29, the term "oxime linkage" lacks antecedent basis.

### ***Response to Argument***

9. Applicant's arguments filed 7/6/06 have been fully considered, and are persuasive to overcome the rejection under 35 USC 102 and 35 USC 103, but are not persuasive to overcome double patenting rejection. However, Applicants' amendment necessitated new ground of rejections under 112 second paragraph which are described in paragraphs 1-8 of this office action.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 20-45 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of 1) US 6,001,364 (claims 1-14), US 6,174,530 B1 (claims 1-13), US 6,217,873 B1 (claims 1-5 and 12-14) or US 6,663,869 B1 (claims 1-17 and 23-26) 2) in view of DeGrado et al (J. Org. Chem. 1982).

Each of the patent disclose homogeneous polyoxime composition comprising baseplate organic molecule (e.g. polypeptide) wherein the baseplate organic molecule is linked to a second organic molecule through an oxime linkage.

The patents however, do not disclose attaching peptide baseplate composition to a solid phase.

DeGrado et al disclose oxime resin as a solid phase reagent for peptide synthesis. A C-terminal amino acid is anchored onto the oxime resin as its oxime-derived ester for peptide coupling. DeGrado et al also disclose the use of oxim resin as solid support is useful for easy cleavage of peptides or proteins from support by hydrazinolysis or by aminolysis (See page 3258, left column and scheme I) for different applications.

Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach peptide baseplate to a solid support such as the solid support to DeGrado et al because use of oxime resin solid support is well

known in the art for solid phase synthesis and for easy cleavage of peptides or linked conjugates for further applications.

### ***Conclusion***

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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EXAMINER  
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LONG V. LE 09/18/06  
SUPERVISORY PATENT EXAMINER  
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